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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,194	06/16/2000	Susan J. Kirst	MBIO99-054CP1M	2288

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Intellectual Propery Group
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EXAMINER
SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,194	KIRST ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/3/00* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *0603* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACTION

1. This action is written in response to applicant's correspondence filed 4/7/03. All previous claims have been cancelled and claims 60-88 have been added and are examined herein. All previous indications of allowed claims and allowable subject matter are hereby WITHDRAWN in view of the new grounds of rejection provided herein. This action is non-final.

2. Please note that the examiner in this application has changed to Examiner Juliet Switzer.

Information Disclosure Statement

3. A review of the file resulted in the identification of a 1449 received by the office on 11/3/00 which had never been signed by an examiner. The signed 1449 is included with this office action. All of the references listed therein have been considered. The references on the 1449 are lined through because they are also listed on at least the 1449 received 7/8/02 which has also been signed by an examiner. It is believed that all information disclosure statements provided by applicant up to this point have now been properly considered.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 60-88 of this application. Since the parent application does not support the claims of the instant invention (see 112 1st paragraph rejection set forth herein) the pending claims are granted priority only to the instant filing date.

Claim Note

5. It is noted that in part (d) of claim 75 applicant refers to "the cDNA clone" but does not particularly recite which cDNA clone is being referred to. The claim previously recites a single cDNA clone, and so the claim is not indefinite per se in view of this recitation, but in the interest of conformity of the claim structure with other portions of the claim, it is recommended that applicant insert the recitation of the particular cDNA clone of interest into part (d) of claim 75.

Claim Objections

6. Claim 67 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of claim 67 is merely a recitation of an inherent property of the nucleic acids of claim 60, and thus it does not appear to further limit the independent claim.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 60-88 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility.

The instantly rejected claims are drawn to nucleic acids, vectors, and host cells which comprise instant SEQ ID NO: 59, SEQ ID NO: 60 or the nucleotide sequence of the cDNA clone

deposited with ATCC as accession number PTA-151, the complements of these molecules or molecules that are fragments of these molecules or that share homology with these molecules. The claimed invention also includes nucleic acids encoding SEQ ID NO: 61 or SEQ ID NO: 63. The nucleic acids are described in the specification as encoding a human TANGO 332 protein (p. 94). The specification asserts that TANGO 332 nucleic acids can be used to "prevent, diagnose, and treat disorders such as brain cancers (e.g., gliomas, astrocytomas, medulloblastomas, ependymomas, Schwnnnomas, pituitary adenoids, teratomas, and the like), disorders of neural connection establishment or maintenance, impaired cognitive function, dementia, senility, Alzheimer's disease, mental retardation, inflammation, immune and autoimmune responses, and the like (specification p. 10)." However, none of these asserted utilities are specific or substantial with regard to the instantly claimed nucleic acids. The asserted utilities are not specific to the claimed nucleic acids because they are generally applicable to any protein that is expressed in the brain—that is, any protein that is expressed in the human brain may have utility in the detection and treatment of any of this diverse listing of possible disorders of the brain. Further, these asserted utilities are not substantial utilities because further experimentation would be required to reasonably confirm if in fact any one of them is applicable to the TANGO 332 protein. Instead, these asserted utilities are an invitation to experiment with the TANGO 332 polypeptides to determine if they are in fact useful in any of methods suggested in the specification. To make such determinations would require extensive research and experimentation by the skilled artisan which would in itself be inventive.

The specification teaches that the TANGO 332 protein has 75.7% identity to human BEF which is a protein that is expressed in human glioma cells but not in brain tumors of non-glial

origin. The specification further teaches at page 100 that it is likely TANGO 332 contains two domains that do not occur in the BEF protein, and that it is likely that these two regions account for the "differences between the physiological roles of TANGO 332 and BEF." However, the specification does not provide any guidance as to what these physiological differences are, or their implications for the activity of TANGO 332 or its role glioma or any other brain disease or disorder. The actual biological activity of the TANGO 332 protein is entirely unconfirmed, and all discussion in the specification of possible biological roles of a TANGO 332 nucleic acid or polypeptide are speculative. Though the TANGO 332 protein has some identity with a protein that is known to be a cancer marker and involved in cancer pathology, there is no evidence of record to support the assertion that the TANGO 332 molecule itself also has similar activity. Atwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the bases of some degree of similarity between sequences." Similarly, Skolnick *et al.* (Trends in Biotech. 2000; 18(1):34-39) teach that even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler *et al.* (Nature Structural Biol. 1997; 4: 527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (summarized in Table 2). Thus, there teachings of the specification are not sufficient to reasonably confirm to the skilled artisan the biological activity of the encoded TANGO 332 molecule, let alone to

determine a specific, substantial, and credible utility for the claimed polynucleotides and related constructs.

Claims 60-88 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 75-81 and 83-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to nucleic acids comprising a nucleotide sequence that is at least 90% identical to SEQ ID NO: 59, 60, or the cDNA clone deposited with ATCC as accession number PTA-151, or fragments comprising at least 400 consecutive nucleotides of SEQ ID NO: 59, 60, or the cDNA clone deposited with ATCC as accession number PTA-151, or a nucleic acid molecule which encodes a fragment of a polypeptide comprising at least 200 consecutive amino acid residues of SEQ ID NO: 61, SEQ ID NO: 63 or the amino acid sequence encoded by the cDNA clone, or a nucleic acid molecule having at least 2600 nucleotides which hybridizes under stringent conditions with a nucleic acid molecule having SEQ ID NO: 59. These claims all encompass nucleic acids which are outside of the sequences disclosed in the specification.

From the specification, it is clear that Applicant is in possession of an isolated nucleic acid molecule which comprises SEQ ID NO: 59, 60, or the cDNA clone deposited with ATCC as accession number PTA-151, an isolated nucleic acid molecule which encodes SEQ ID NO: 61, SEQ ID NO: 63 or the amino acid sequence encoded by the cDNA clone. However, the rejected claims encompass nucleic acid sequences that are variant from those described and which encompass nucleic acids encoding proteins which differ from those disclosed in both structure and possible function. While the claims set forth putative functions for the encompassed nucleic

acids (i.e. the encoded polypeptide exhibits a biological function of TANGO 332 protein) the recited functions are not sufficient to establish a structure/function relationship that helps to define the claimed invention and provide descriptive support for the broad genus. Furthermore, applicant has not demonstrated that they are in possession of the polynucleotides encoding proteins having the recited functions as applicant's specification has not provided any guidance or disclosure that would aid one in determining which nucleic acids of all of the possible nucleic acids encompassed within the claims have the functions recited in the claims. There not a correlative structure/function relationship set forth as the functions recited in the claims are general in nature and could be the result of many different structural motifs. Thus, the functions do not help to define an invention that applicant was in possession of as one can not use the recited functions to predict the structures of the encompassed nucleic acids. The specification does not clearly set forth or demonstrate any particular function for a TANGO 332 protein, and in fact the specification teaches that the function of the TANGO 332 protein is physiologically different from the human BEF, but the specification does not demonstrate or even suggest what this difference may be (p. 100 of the specification).

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequences of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any proteins modified by addition, insertion, deletion, substitution or inversion with the disclosed sequences but possessing one or more nucleic acid differences such that a different amino acid sequence is encoded which retains the same activity as the TANGO 332 protein, especially in light of the fact that the actual functionality of the TANGO 332 protein is largely unknown and is only the subject of speculation in the specification.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 75-79 and 81 are rejected under 35 U.S.C. 102(a) and 102(b) as being anticipated by NI *et al.* (WO 98/31800).

Ni *et al.* teach an isolated nucleic acid molecule comprising at least 400 consecutive nucleotides of SEQ ID NO: 59, SEQ ID NO: 60 or the nucleotide sequence of the cDNA clone deposited with ATCC as Accession number PTA-151. Specifically, at least nucleotides 640-

1074 of instant SEQ ID NO: 60 are identical to nucleotides 463-897 of SEQ ID NO: 19 as disclosed by Ni *et al.* (see Figure 10 of Ni *et al.*). An alignment of the two sequences follows, the numbering on the top row refers to instant SEQ ID NO: 60 while the numbering on the bottom row refers to the sequence taught by Ni *et al.*

```
Qy     640 AGGTATCCCATCCAGACCCCACGAGAGGCCTGTTACGGAGACATGGATGGCTTCCCCGGG 699
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     463 AGGTATCCCATCCAGACCCCACGAGAGGCCTGTTACGGAGACATGGATGGCTTCCCCGGG 522

Qy     700 GTCCGGAACTATGGTGTGGTGGACCCGGATGACCTCTATGATGTGTACTGTTATGCTGAA 759
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     523 GTCCGGAACTATGGTGTGGTGGACCCGGATGACCTCTATGATGTGTACTGTTATGCTGAA 582

Qy     760 GACCTAAATGGAGAACTGTTCCTGGGTGACCCTCCAGAGAAGCTGACATTGGAGGAAGCA 819
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     583 GACCTAAATGGAGAACTGTTCCTGGGTGACCCTCCAGAGAAGCTGACATTGGAGGAAGCA 642

Qy     820 CGGGCGTACTGCCAGGAGCGGGGTGCAGAGATTGCCACCACGGGCCAACTGTATGCAGCC 879
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     643 CGGGCGTACTGCCAGGAGCGGGGTGCAGAGATTGCCACCACGGGCCAACTGTATGCAGCC 702

Qy     880 TGGGATGGTGGCCTGGACCACTGCAGCCCAGGGTGGCTAGCTGATGGCAGTGTGCGCTAC 939
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     703 TGGGATGGTGGCCTGGACCACTGCAGCCCAGGGTGGCTAGCTGATGGCAGTGTGCGCTAC 762

Qy     940 CCCATCGTCACACCCAGCCAGCGCTGTGGTGGGGGCTTGCCTGGTGTCAAGACTCTCTTC 999
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     763 CCCATCGTCACACCCAGCCAGCGCTGTGGTGGGGGCTTGCCTGGTGTCAAGACTCTCTTC 822

Qy    1000 CTCTTCCCCAACCAGACTGGCTTCCCCAATAAGCACAGCCGCTTCAACGTCTACTGCTTC 1059
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     823 CTCTTCCCCAACCAGACTGGCTTCCCCAATAAGCACAGCCGCTTCAACGTCTACTGCTTC 882

Qy    1060 CGAGACTCGGCCCAG
           |||||||||||||||
Db     883 CGAGACTCGGCCCAG
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In a similar fashion, nucleotides 812-1246 of instant SEQ ID NO: 59 are identical to nucleotides 4630897 of SEQ ID NO: 19 taught by Ni *et al.* An additional alignment is not provided because it is duplicative of the alignment illustrated above.

It is noted that the rejected claims include functional limitations which require that the encoded polypeptide "exhibits a biological function of TANGO 332 protein" and then in

independent claims further elucidate the putative functions of the TANGO 332 protein. With regard to the broad recitation of claim 75, the "a biological function of a TANGO 332 protein" would encompass any function of the polypeptide, including to act as a substrate for a protease. The polypeptide encoded by the polynucleotide taught by Ni *et al.* would have this function. With regard to the further more specific functions recited in the dependent claims, Ni *et al.* teach that their SEQ ID NO: 19 encodes a brain-enriched hyaluronan-binding factor (p. 64), and such a protein would inherently have the functions listed in the dependent claims herein. Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'" In the instant case the nucleic acid meets all of the structural limitations required by the claims and appears to be substantially identical to the claimed nucleic acid.

13. Claims 84-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada *et al.* (The Journal of Biological Chemistry, Vol. 269, No. 13, p. 10119-10126, 1994).

Yamada *et al.* teach an isolated nucleic acid having a length of at least 2600 nucleotides, wherein the nucleic acid hybridizes under stringent hybridization conditions with a nucleic acid molecule having the sequence SEQ ID NO: 59. In particular, in Fig. 3, Yamada *et al.* disclose the complete cDNA sequence of bovine brevican core protein. This nucleic acid is 3259 nucleotides in length and share 58% overall similarity with instant SEQ ID NO: 59 and

comprises a portion that shares 87.9% local similarity with instant SEQ ID NO: 59. An alignment of the two sequences is provided as follows, the sequence on the top row is instant SEQ ID NO: 59 and the sequence on the bottom row is the sequence taught by Yamada *et al.*

```
Qy    163 AGCCTGCAGCATGGCCCAGCTGTTCCTGCCCCTGCTGGCAGCCCTGGTCCTGGCCCAGGC 222
          | ||||||||||||||||  |||||||||||||| ||||||| ||||||| ||||||  |
Db    102 ATCCTGCAGCATGGCCCCACTGTTCCTGCCCCTCCTGGCAACCCTGGTTCTGGCCTGGAT 161

Qy    223 TCCTGCAGCTTTAGCAGATGTTCTGGAAGGAGACAGCTCAGAGGACCGCGCTTTTCGCGT 282
           ||||  ||  ||  ||  |||| |||||||||||||||||||||||| | ||  || |||||
Db    162 CCCTGTGGCCTTGGCTGATGCTCTGGAAGGAGACAGCTCAGAGGACAGGGCCTTCCGCGT 221

Qy    283 GCGCATCGCGGGCGACGCGCCACTGCAGGGCGTGCTCGGCGGCGCCCTCACCATCCCTTG 342
          |||||||||||||||||||| |||||||||||||| |||||||||||||||||||| ||
Db    222 GCGCATCGCGGGCGACGCGCCGCTGCAGGGCGTGCTGGGCGGCGCCCTCACCATCCCATG 281

Qy    343 CCACGTCCACTACCTGCGGCCACCGCCGAGCCGCCGGGCTGTGCTGGGCTCTCCGCGGGT 402
          ||||||  |||||||||||||||  |||||||||||||||| | || ||||||  ||||||||
Db    282 CCACGTTCACTACCTGCGGCCGTCGCCGAGCCGCCGGGCCGCGCAGGGCTCCCCGCGGGT 341

Qy    403 CAAGTGGACTTTCCTGTCCCGGGGCCGGGAGGCAGAGGTGCTGGTGGCGCGGGGAGTGCG 462
           ||||||||  |||||||||  | ||||||||||  ||||||| ||||||||||   | ||
Db    342 TAAGTGGACCTTCCTGTCCGGCGGCCGGGAGGCCGAGGTGCTAGTGGCGCGGGGCCTACG 401

Qy    463 CGTCAAGGTGAACGAGGCCTACCGGTTCCGCGTGGCACTGCCTGCGTACCCAGCGTCGCT 522
          ||||||||||| ||||||||||||||||||||||||||||||| ||||| ||||| ||
Db    402 CGTCAAGGTGAGCGAGGCCTACCGGTTCCGCGTGGCACTGCCTGCTTACCCGGCGTCACT 461

Qy    523 CACCGACGTCTCCCTGGCGCTGAGCGAGCTGCGCCCCAACGACTCAGGTATCTATCGCTG 582
          |||||||||||||||||  ||||||  |||||||| |||||||||||||  ||  ||  |||||
Db    462 CACCGACGTCTCCCTGGTGCTGAGTGAGCTGCGGCCCAACGACTCAGGCATTTACCGCTG 521

Qy    583 TGAGGTCCAGCACGGCATCGATGACAGCAGCGACGCTGTGGAGGTCAAGGTCAAAGGGGT 642
          |||||||||||||||||||| |||||||||||||| ||||||||||||||||||||||||
Db    522 CGAGGTCCAGCACGGCATCGACGACAGCAGCGACGCGGTGGAGGTCAAGGTCAAAGGGGT 581

Qy    643 CGTCTTTCTCTACCGAGAGGGCTCTGCCCGCTATGCTTTCTCCTTTTCTGGGGCCCAGGA 702
          ||||||||||||||  ||||||||||||||||  ||||||||||   ||||||||||||
Db    582 CGTCTTTCTCTACCGGGAGGGCTCTGCCCGCTACGCTTTCTCCTTCGCTGGGGCCCAGGA 641

Qy    703 GGCCTGTGCCCGCATTGGAGCCCACATCGCCACCCCGGAGCAGCTCTATGCCGCCTACCT 762
          ||||||||||||||| |||||||  |||||||| ||||||||||||||||||||||||||
Db    642 GGCCTGTGCCCGCATCGGAGCCCGAATCGCCACTCCGGAGCAGCTCTATGCCGCCTACCT 701

Qy    763 TGGGGGCTATGAGCAATGTGATGCTGGCTGGCTGTCGGATCAGACCGTGAGGTATCCCAT 822
          ||||||||||| || ||||| |||||||||||||| || ||||||||||||||||||||
Db    702 CGGGGGCTATGAACAGTGTGACGCTGGCTGGCTGTCCGACCAGACCGTGAGGTATCCCAT 761

Qy    823 CCAGACCCCACGAGAGGCCTGTTACGGAGACATGGATGGCTTCCCCGGGGTCCGGAACTA 882
          ||||||  |||||||||||||||| |||||||||||||||||| ||||||||||||||
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Db     762 CCAGACGCCACGAGAGGCCTGTTATGGAGACATGGATGGCTTCCCTGGGGTCCGGAACTA 821

Qy     883 TGGTGTGGTGGACCCGGATGACCTCTATGATGTGTACTGTTATGCTGAAGACCTAAATGG 942
           || ||||| ||||| |||||||||||||||| |||||||||||||||| ||||||||
Db     822 CGGAGTGGTCGACCCCGATGACCTCTATGATGTTTACTGTTATGCTGAAGAACTAAATGG 881

Qy     943 AGAACTGTTCCTGGGTGACCCTCCAGAGAAGCTGACATTGGAGGAAGCACGGGCGTACTG 1002
           ||| |||||||||||||| ||||||||| |||||||| |||||||| || ||| | |||||
Db     882 AGAGCTGTTCCTGGGTGCCCCTCCAGACAAGCTGACCTTGGAGGAGGCGCGGACATACTG 941

Qy    1003 CCAGGAGCGGGGTGCAGAGATTGCCACCACGGGCCAACTGTATGCAGCCTGGGATGGTGG 1062
           |||||||||||||||  ||||||| ||||| ||||| ||||||||||||||||||||||||
Db     942 CCAGGAGCGGGGTGCTAAGATTGCAACCACCGGCCAGCTGTATGCAGCCTGGGATGGTGG 1001

Qy    1063 CCTGGACCACTGCAGCCCAGGGTGGCTAGCTGATGGCAGTGTGCGCTACCCCATCGTCAC 1122
           |||||||| ||||||| | || ||||| ||||||||||||||||||||||||||||||||
Db    1002 CCTGGACCGCTGCAGCTCTGGCTGGCTGTCTGATGGCAGTGTGCGCTACCCCATCGTCAC 1061

Qy    1123 ACCCAGCCAGCGCTGTGGTGGGGGCTTGCCTGGTGTCAAGACTCTCTTCCTCTTCCCCAA 1182
           |||||||||||||||||||||||| | ||||||||||||||||||||||||||||||||
Db    1062 CCCCAGCCAGCGCTGTGGTGGGGGCCTCCCTGGTGTCAAGACTCTCTTCCTCTTCCCCAA 1121

Qy    1183 CCAGACTGGCTTCCCCAATAAGCACAGCCGCTTCAACGTCTACTGCTTCCGAGACTCGGC 1242
           |||||||||||||||||| |||||||||||||||||||||||||||||||||||||||| ||
Db    1122 CCAGACTGGCTTCCCCAACAAGCACAGCCGCTTCAACGTCTACTGCTTCCGAGACTCTGC 1181

Qy    1243 CCAGCCTTCTGCCATCCCTGAGGCCTCCAACCCAGCCTCCAACCCAGCCTCTGATGGACT 1302
           |||||||||||||||||||||||  ||||||||||||  |||  |||||||||| |||
Db    1182 CCAGCCTTCTGCCATCCCTGAGGCAGCCAACCCAGCCTCTCACCTGGCCTCTGATGCACT 1241

Qy    1303 AGAGGCTATCGTCACAGTGACAGAGACCCTGGAGGAACTGCAGCTGCCTCAGGAAGCCAC 1362
           || || || |||||||||| |||||||||||||||||| ||||||| ||||||||
Db    1242 GGAAGCCATTGTCACAGTGACTGAGACCCTGGAGGAACTGAAGCTGCCCCAGGAAGCTGT 1301

Qy    1363 AGAGAGTGAATCCCGTGGGGCCATCTACTCCATCCCCATCATGGAGGACGGAGGAGGTGG 1422
           || || || ||||| || |||||||| |||||||||| || ||||| ||||| |||||
Db    1302 GGAAAGCGAGTCCCGAGGAGCCATCTATTCCATCCCCATTATAGAGGATGGAGGTGGTGG 1361

Qy    1423 AAGCTCCACTCCAGAAGACCCAGCAGAGGCCCCTAGGACGCTCCTAGAATTTGAAACACA 1482
           |||||||||||||||||||||||||||||||||| || |||||||||| ||||| ||
Db    1362 GAGCTCCACTCCAGAAGACCCAGCAGAGGCCCCTAGAACCCTCCTAGAATTCGAAACCCA 1421

Qy    1483 ATCCATGGTACCGCCCACGGGGTTCTCAGAAGAGGAAGGTAAGGCATTGGAGGAAGAAGA 1542
           |||||| || || ||   ||||| |||||||||||||| ||||  |||||| |||||||
Db    1422 ATCCATTGTGCCTCCATTGGGGTCCTCAGAAGAGGAAGGCAAGGTGTTGGAGCAAGAAGA 1481

Qy    1543 GAAATATGAAGATGAAGAAGAGAAAGAGGAGGAAGAAGAAGAGGAGGAGGTGGAGGATGA 1602
           ||||||    | |||||||||||||| ||||||||||||||||||||||||||||||||
Db    1482 GAAATACAGGGGTGAAGAAGAGAAAGAAGAGGAAGAAGAAGAGGAGGAGGTGGAGGATGA 1541

Qy    1603 GGCTCTGTGGGCATGGCCCAGCGAGCTCAGCAGCCCGGGCCCTGAGGCCTCTCTCCCCAC 1662
           ||| |||||||| |||||||| |||||||||||| || ||| |||||| ||||||||||
Db    1542 GGCCCTGTGGGCCTGGCCCAGTGAGCTCAGCAGCCTGGACCCAGAGGCCCCTCTCCCCAC 1601
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Qy    1663 TGAGCCAGCAGCCCAGGAG---AAGTCACTCTCCCAGGCGCCAGCAAGGGCAGTCCTGCA 1719
           |||||| |   | |||||       | |   |   | | ||||  ||||| | ||| ||
Db    1602 TGAGCCCGTTCCAGAGGAGTCACTCACCCAGGCATCGCCTCCAGTGAGGGCTGCCCTCCA 1661

Qy    1720 GCCTGGTGCATCACCACTTCCTGATGGAGAGTCAGAAGCTTCCAGGCCTCCAAGGGTCCA 1779
           |||||||| ||||||||  ||  |||  ||| |||| ||| ||||||||||||||||||
Db    1662 GCCTGGTGTATCACCACCACCCTATGATGAGCCAGAGGCTCCCAGGCCTCCAAGGGTCCT 1721

Qy    1780 TGGACCACCTACTGAGACTCTGCCCACTCCCAGGGAGAGGAACCTAGCATCCCCATCACC 1839
           ||||||||| ||  |||| |||||||||| |||||| ||||||| ||||||||  ||||
Db    1722 TGGACCACCCACCAAGACCCTGCCCACTCCTAGGGAGGGGAACCTGGCATCCCCCCCACC 1781

Qy    1840 TTCCACTCTGGTTGAGGCAAGAGAGGTGGGGGAGGCAACTGGTGGTCCTGAGCTATCTGG 1899
           |||||||||||||| |||||||||| | | |||||  ||||| |||||||||| |||||
Db    1782 TTCCACTCTGGTTGGGGCAAGAGAGATAGAGGAGGAGACTGGGGGTCCTGAGCTCTCTGG 1841

Qy    1900 GGTCCCTCGAGGAGAGAGCGAGGAGACAGGAAGCTCCGAGGGTGCCCCTTCCCTGCTTCC 1959
           || |||||||||||||| |||||||||||||||||||| ||||||||||||||||||
Db    1842 GGCCCCTCGAGGAGAGAGTGAGGAGACAGGAAGCTCCGAGGATGCCCCTTCCCTGCTTCC 1901

Qy    1960 AGCCACACGGGCCCCTGAGGGTACCAGGGAGCTGGAGGCCCCCTCTGAAGATAATTCTGG 2019
           |||||||||||||||| || |||||||| |||||| |||||||||||| |||||  |
Db    1902 AGCCACACGGGCCCCTGGGGATACCAGGGATCTGGAGACCCCCTCTGAAGAGAATTCCAG 1961

Qy    2020 AAGAACTGCCCCAGCAGGGACCTCAGTGCAGGCCCAGCCAGTGCTGCCCACTGACAGCGC 2079
           |||||||| |||||||||||| |||||||  |||||||||||||||||||||||||| ||
Db    1962 AAGAACTGTCCCAGCAGGGACTTCAGTGCGTGCCCAGCCAGTGCTGCCCACTGACAGTGC 2021

Qy    2080 CAGCCGAGGTGGAGTGGCCGTGGTCCCCGCATCAGGTAATTCTGCCCAAGGCTC 2133
           |||||| |||||||||||||||| |||| |||||||| | | || ||    || |
Db    2022 CAGCCGTGGTGGAGTGGCCGTGGCCCCCTCATCAGGTGACTGTGTCCCCAGCCC 2075
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It is noted that the rejected claims include functional limitations which require that the claimed nucleic acid molecule be able to hybridize to instant SEQ ID NO: 59 under "stringent conditions," with specific stringency conditions being listed. Given the high degree of similarity between the sequence taught by Yamada *et al.* and the instant SEQ ID NO: 59, hybridization under stringent conditions would be expected. Likewise, hybridization under the conditions recited in claim 85 would also be expected. Furthermore, claims 86-87 recite functional limitations requiring that the encoded polypeptide "exhibits a biological function of TANGO 332 protein" and then further elucidate the putative functions of the TANGO 332 protein. With regard to the broad recitation of claim 86, the "a biological function of a TANGO 332 protein"

would encompass any function of the polypeptide, including to act as a substrate for a protease. The polypeptide encoded by the polynucleotide taught by Yamada *et al.* would have this function. With regard to the further more specific functions recited in claim 87, Yamada *et al.* are silent as to whether or not the polypeptide they disclose has any or all of these functions. Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'" In the instant case the nucleic acid meets all of the structural limitations required by the claims and appears to be substantially identical to the claimed nucleic acid, and thus it is concluded that the products of the prior art are the same as the claimed products.

Response to Remarks

As the issues presented in this office action are newly presented, applicant's remarks are not directed towards the pending rejections. Therefore, there are no arguments to be answered at this time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Switzer
Examiner
Art Unit 1634

June 20, 2003

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600